Atty. Docket No: 2857 (203-3424 PCTUS)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Richard D. Gresham EXAMINER: Thomas M. McEvoy

SERIAL NO.: 10/522,914 GROUP: 4123

FILED: January 28, 2005 DATED: March 19, 2010

FOR: **TOOL MEMBER COVER AND COVER DEPLOYMENT DEVICE**

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P.O. Box 1450
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BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action dated August 5, 2009 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20 (b)(2).

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a/ Covidien) having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

II. RELATED APPEALS AND INTERFERENCES

Appellant's legal representative and/or the assignee of Appellant's interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: March 19, 2010

Suzanne L. Forlani

III. STATUS OF CLAIMS

The instant application was originally filed with 26 Claims. Claims 27-33 were added during prosecution. Claims 3-5 and 27-29 have been cancelled. Independent Claims 1, 21 and 30, and dependent Claims 2, 6-20, 22-26 and 31-33 are pending in this application and are involved in this Appeal. Each of these claims stands finally rejected as set forth in the Final Office Action mailed August 17, 2009 (the "Final Office Action") and the Advisory Action mailed December 2, 2009 (the "Advisory Action"). An accurate copy of Claims 1, 2, 6-26 and 30-33 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed December 2, 2009 indicates that the Request for Reconsideration filed on November 16, 2009 has been considered but does not place the application in condition for allowance. Thus, the claims are as amended in the Request for Reconsideration filed November 16, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 recites a surgical instrument including a body portion, a tool assembly supported on the distal end of the body portion and an elongated cover supported about the body portion of the instrument. (Page 6, lines 14-16). The elongated cover is formed from a collapsible material. (Page 6, lines 6-8). The elongated cover includes a substantially tubular configuration having open proximal and distal ends. (Page 6, lines 8-10). The elongated cover is movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly. (Page 9, lines 3-18). When the

elongated cover is in the first position the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position. (Page 8, lines 6-9). The surgical instrument further includes a cover deployment device at least partially disposed about the body portion between the body portion and the elongated cover when the elongated cover is in the first position. (Page 7, lines 5-8). The cover deployment device is in releasable engagement with the cover and is advanceable along the body portion to move the cover from the first position to the second position. (Page 9, lines 3-18).

Claim 21 recites a method of performing a surgical procedure. The method includes the following steps of providing a surgical instrument including a body portion, a tool assembly, a cover deployment device and a cover. (Page 6, lines 14-16). The distal end of the cover is secured about the instrument adjacent a proximal end of the tool assembly. (Page 8, lines 6-9). The cover deployment device is positioned on the body portion and the cover is positioned about the cover deployment device such that the cover is movable from a first position wherein the tool assembly is uncovered to a second position wherein the tool assembly is at least partially covered by advancing the cover deployment device along the body portion. (Page 8, lines 19-21). The method further includes the steps of positioning the surgical instrument adjacent a surgical site and performing a surgical operation on desired tissue, moving the cover from the first position to the second position by advancing the cover deployment device to invert the cover at least partially over the tool assembly, and subsequently removing the surgical instrument from the surgical site, while maintaining the cover at least partially over the tool assembly. (Page 9, lines 3-18).

Claim 30 recites a surgical instrument for insertion into a body lumen. The surgical instrument includes an elongated body portion having a first diameter and an outer surface. The surgical instrument further includes a stationary shell assembly supported on a distal end of the elongated body portion having a plurality of surgical staples therein. (Page 8, lines 16-17). A cover is fitted about the elongated body portion. (Page 8, lines 6-9). The elongated cover is movable from a first proximal position to a second position to cover the stationary shell assembly. (Page 8, lines 19-21). The surgical instrument also includes a cover deployment member positioned about the elongated body portion between the elongated body portion and the cover. (Page 7, lines 5-8). The cover deployment is slidable in a distal direction along the body portion to move the cover to the second position. (Page 9, lines 3-18).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are on appeal:

i) whether Claims 1, 2 and 6-17 are anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,665,073 to Bulow et al. ("Bulow");

ii) whether Claims 1, 2, 11 and 13-17 are anticipated under 35 U.S.C. § 102(e) by U.S. Patent Application Publication No. 2003/0139767 to Jespersen ("Jespersen");

iii) whether Claims 30-33 are anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,318,221 to Green et al. ("Green");

iv) whether Claims 18-20 are obvious under 35 U.S.C. § 103(a) over Bulow in view of U.S. Patent No. 6,024,741 to Williamson et al. ("Williamson");

v) whether Claims 21, 25 and 26 are obvious under 35 U.S.C. § 103(a) over Jespersen; and,

vi) whether Claims 18-20, 22-24 and 30 are obvious under 35 U.S.C. § 103(a) over Jespersen in view of Williamson.

VII. ARGUMENT

A. Bulow Fails To Anticipate or Render Obvious The Surgical Instrument As Recited In Claims 1, 2 and 6-17

Claims 1, 2 and 6-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bulow.

Under 35 U.S.C. § 102(b), "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. Appellant respectfully submit that Bulow fails to disclose each and every element recited in independent Claim 1, either expressly or inherently.

Independent Claim 1 recites a surgical instrument including a body portion, a tool assembly supported on the distal end of the body portion, an elongated cover supported about the body portion of the instrument, and a cover deployment device at least partially disposed about the body portion between the body portion and the elongated cover when the elongated cover is in the first position. The elongated cover is formed from a collapsible material and includes a substantially tubular configuration having open proximal and distal ends. The elongated cover is movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly. When the elongated cover is in

the first position the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position. The cover deployment device is in releasable engagement with the cover and is advanceable along the body portion to move the cover from the first position to the second position.

Bulow discloses a protective sheath and securement apparatus for surgical conduits shown in FIGS. 3 and 4 below. The apparatus of Bulow includes a fabric sleeve 12, a shield 14 mounted to the distal end of the sleeve 12, and a sheath guide 70 configured for deploying sleeve 12. Guide 70 includes opposed guide members 72 and 73. Each guide member 72, 73 includes a semicylindrical surface 74, 75, respectively, and a semicircular flange 76, 77, respectively. Semicircular flanges 76, 77 collectively provide a bonding surface for bonding a distal end 13 of fabric sleeve 12 to shield 14. In particular and with specific reference to FIG. 4, distal end 13 of fabric sleeve 12 is bonded to shield 14 as shown by a broken line at 13a while a bonding surface 15 on shield 14 to which distal end 13 is bonded is delineated by a broken line 15a. Semicircular flanges 76, 77 in effect sandwich distal end 13 against bonding surface 15 to present to the user a protective sheath 10 having a smooth profile through which collective conduits 60 can be passed. Semicircular flanges 76, 77 also secure retainer strings 18, 19 to sheath 14. Guide member 70 serves as a basal element over which fabric sleeve 12 can be telescopically folded.

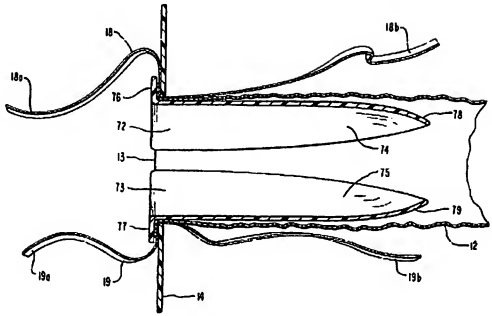
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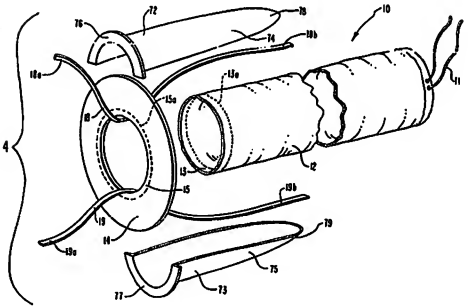
FIG. 3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15a
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19b
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19a
75
77
73

FIG. 4

With reference to FIG. 1 of Bulow, reproduced below, in use, conduits 32, 42, 52 (collectively, conduits 60) are inserted through shield 14 and fabric sleeve 12 and a drawstring 11 is tied about the conduits. Next, shield 14 and guide 70 are moved along the conduits (in a direction away from drawstring 11) to unfold fabric sleeve 12 about the conduits. Sleeve 10 is then secured to a surgical drape 24 using hemostats 26. Protective sleeve 10 functions to protect the conduits from liquids to facilitate cleanup upon completion of the surgical procedure. Following completion of the surgical procedure, drawstring 11 is released and conduits 32, 42 and 52 are individually pulled through fabric sleeve 12 and shield 14.

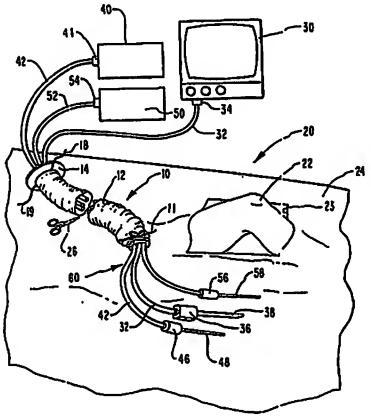


FIG. 1

Appellant respectfully submits that Bulow fails to disclose the surgical instrument recited in Claim 1. More specifically, Bulow fails to disclose the following elements recited in Claim 1:

> 1) "an elongated cover supported about the body portion of an instrument"
>
> 2) "the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly;
>
> 3) "...the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly..."; and
>
> 4) "a cover deployment device at least partially disposed about the body portion [of the surgical instrument] between the body portion and the elongated cover when the cover is in the first position, the cover deployment device being in releasable engagement with the cover and being advanceable along the body portion to move the cover from the first position to the second position."

In contrast to the surgical instrument recited in Claim 1, Bulow's protective sheath is not supported about, nor does it function to protect or shield a surgical instrument having a tool assembly. Rather, Bulow's sheath shields hoses or conduits for supplying air, water, power, etc. to a surgical site. Thus, Bulow's sheath is not supported about the body portion of an instrument.

The sheath of Bulow is not movable about the body portion of an instrument from a first position located proximal of the tool assembly to a second position at least partially encompassing the tool assembly. As discussed above, Bulow's sheath is not received about the body portion of an instrument, and therefore, cannot be moved from such a position located

proximal of the tool assembly to a second position at least partially encompassing the tool assembly.

As discussed in detail above, the distal end of Bulow's sheath is not secured to a surgical instrument adjacent a tool assembly, but rather is secured about a plurality of hoses 60 and to a surgical drape 24 to effectively orient the conduits. Since Bulow's guide 70 is fixedly secured to sleeve 12, sleeve 12 cannot be inverted about a tool assembly. As such, the distal end of Bulow's sheath is not secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly.

In addition, Bulow's guide 70 is not in releasable engagement with the sheath and therefore is not advanceable along a body portion of a surgical instrument to move the sheath along the body from the first position to the second position, where the sheath is at least partially covering the tool assembly. In contrast, the apparatus of Bulow operates by first advancing guide 70 about hoses 60 to a position closer to the surgical site, cinching the drawstring 11, and then pulling guide 70 away from the surgical site to deploy sleeve 12 about the hoses.

In the Final Office Action mailed August 17, 2009, the Examiner stated the following:

> Guide member 72 and 73 can be considered as cover deployment device which are between the cover and body portion(s) and which are in releasable engagement with the cover. When members 18 and 19 are released as in Figure 1 and the drawstring 11 is secured to the body portion adjacent the tool assemblies (which would be a reasonable configuration for this apparatus), the cover deployment device could be advanced along the body portion to move the cover from the first position to the second position.

Contrary to the Examiner's statements in the Final Office Action, Bulow does not disclose a deployment device which is in releasable engagement with the cover. Bulow's

sheath guide 70 includes opposed guide members 72, 73, which the Examiner identified as the cover deployment device, each of which include a semicircular flange 76, 77, respectively. Semicircular flanges 76, 77 collectively provide a bonding surface for fixedly bonding a distal end 13 of fabric sleeve 12 to shield 14. In a first or retracted configuration, sleeve 12 is completely received about and supported on guide members 72, 73. In the second or deployed configuration, the distal end 13 of sleeve 12 is received about and supported on guide member 72, 73. At all times, distal end 13 of sleeve 12 is fixedly secured to guide members 72, 73. Thus, Bulow's sleeve 12 is fixedly secured to guide 70, and is not releasably engaged with the cover as recited in Claim 1.

Appellant notes that the presently claimed instrument including the cover and cover deployment device is provided to manipulate, identify, treat, repair and/or excise tissue within a body cavity. The cover and cover deployment device of the instrument are provided to deploy and shield a tool assembly of the instrument, which may have contacted diseased tissue during a surgical procedure, after the tool assembly has been used within the body cavity and prior to removal of the instrument/tool assembly from the body cavity. The releasablity of the cover from the cover deployment device, as recited in Claim 1, facilitates effective use of the cover in such an environment.

For any one or all of the distinctions identified above, Appellant submits that Bulow does not anticipate the surgical instrument recited in Claim 1. Accordingly, Appellant submits that Claim 1 is in condition for allowance.

Claims 2 and 6-17 depend from Claim 1. For at least the reasons discussed above with respect to Claim 1, *inter alia*, Appellant submits that Claims 2 and 6-17 are also in condition

for allowance.

Therefore, Appellant submits that the rejection of Claims 1, 2 and 6-17 under 35 U.S.C. § 102(b) should be reversed.

B. Jespersen Fails To Anticipate or Render Obvious The Surgical Instrument As Recited In Claims 1, 2, 11 And 13-17

Claims 1, 2, 11 and 13-17 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Jespersen.

As noted above, under 35 U.S.C. § 102(b), "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. Appellant respectfully submits that Jespersen fails to disclose each and every element recited in independent Claim 1, either expressly or inherently.

Jespersen discloses an organ or tissue retrieval bag arrangement 10 shown in FIGS. 2 and 7, reproduced below, including a bag 12 having a first or proximal end 14 and a second or distal end 16. The distal end 16 of the retrieval bag 12 has a pair of generally tapered tubular-shaped grasper receiving tips 18 and 20 extending therefrom to receive grasper jaws 34 and 36, respectively. In use, grasper device 32, including retrieval bag 10, is inserted into a patient through a trocar or other opening in the body until the proximal end 14, including beading 28, is received past the distal end of the trocar. The tissue to be excised is next grasped within jaws 34 and 36 of grasper device 32. Once the tissue has been excised, a second grasper device 44 is used to grab beading 28 at the proximal end 14 of retrieval bag 12 and pull retrieval bag 12 in a distal

direction about the excised tissue. The specification continues, at paragraph [0041],

> ...The original outer side 48 of the organ retrieval bag 12 thus becomes the inner side of the tissue containment bag once it has been pulled distally from the grasper device 32 and about the tissue/organ "T" being retrieved, as exemplified in FIG. 7. The tissue "T" then may be safely enveloped within the everted organ retrieval bag 12 and removed through the trocar 40 or surgical opening in the patient, without loss of any contaminated fluid or without contaminating tissue components escaping therefrom.

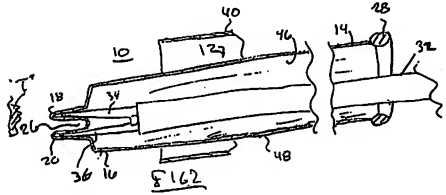


FIG 2

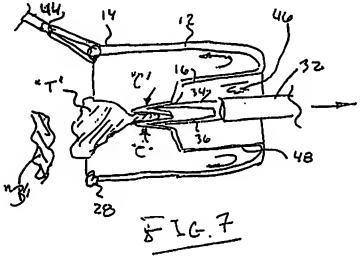


FIG. 7

Claim 1 recites, inter alia, "a cover deployment device at least partially disposed about the body portion between the body portion and the elongated cover when the elongated cover is in the first position...". Appellant respectfully submit that Jespersen does not disclose the recited claim elements. More specifically, as discussed above, Jespersen uses a separate grasper device 44 to invert the retrieval bag 12. Contrary to the Examiner's assertion, during normal use forceps 44 is not disposed, even partially, about the body portion of device 32. Furthermore, at no point during use of bag 12 is the "cover deployment device" (forceps 44) placed between the bag 12 and the body of device 32. This is clearly evident in FIG. 7, as shown above. Thus, Appellant respectfully submits that Jespersen does not anticipate Claim 1 and that Claim 1 is patentable over Jespersen and is in condition for allowance.

Claims 2, 11 and 13-17 depend from Claim 1. For at least the reasons discussed above with regard to Claim 1, *inter alia*, Appellants submit that Claims 2, 11 and 13-17 are also in condition for allowance.

Therefore, Appellant respectfully requests that the rejection of Claims 1, 2, 11 and 13-17 under 35 U.S.C. § 102(b) should be reversed.

C. Green Fails To Anticipate or Render Obvious The Surgical Instrument As Recited In Claims 30-33

Claims 30-33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Green.

As noted above, under 35 U.S.C. § 102(b), "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. Appellant respectfully submit that Green

fails to disclose each and every element recited in independent Claim 30, either expressly or inherently.

With reference to FIGS. 15A and 15B, reproduced below, Green discloses an instrument having a housing 134 and an anvil member 136. A cartridge assembly 137 is received on a relatively wider section 134B of housing 134. Cartridge assembly 137 includes a plurality of staples (not shown). A collar 127 is slidably positioned over a proximal end of housing 134 and proximal arms 136B of anvil member 136 to effect pivotable movement of the anvil towards housing 134.

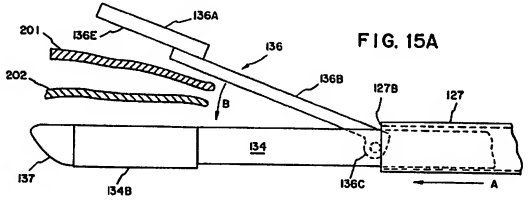


FIG. 15A

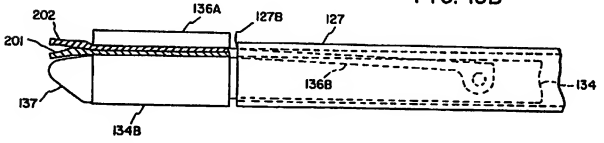


FIG. 15B

Appellant respectfully submits that Green does not disclose each and every element recited in Claim 30. More specifically, Green does not disclose a surgical instrument including a shell assembly having a plurality of surgical staples and an elongated cover movable from a first

proximal position to a second position to cover the stationary shell assembly. As discussed above, Green discloses an instrument including a housing 134 having a relatively wider distal end 134B configured to receive a cartridge assembly 137. Collar 127 is configured to slide distally to approximate anvil member 136 towards housing 134, and its movement thereby advances over a proximal end of housing 134. However, as shown in FIG. 15B, collar 127 includes a diameter smaller than that of distal end 134B of housing 134 and anvil plate 136A, thereby preventing collar 127 from covering distal end 134B and anvil plate 136. Therefore, collar 127 is not movable from a first position to a second position to cover the portion of housing 134 including cartridge assembly 137 (distal end 134B).

Appellant notes that the sole purpose of collar 127 is to pivot anvil member 136. Collar 127 is not capable of, nor is it intended to, cover the cartridge assembly 137.

In the Advisory Action, the Examiner stated the following:

> FIG. 11 clearly shows that the member 136B overlays member 134B and the cover is clearly intended to completely cover member 136B in order to fully clamp and staple tissue.

Appellants submit that the Examiner has completely misconstrued and/or ignored the clear and unequivocal disclosure provided in Green which is exemplified in at least FIG. 15B, which shows that collar 127 in its advanced position spaced proximally of cartridge assembly 137 and the distal end 134B of housing 134.

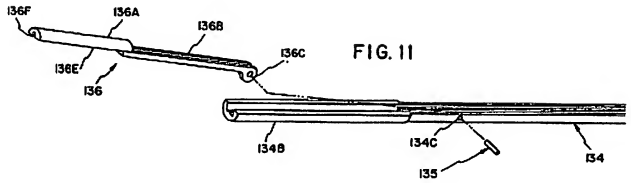


FIG. 11

For any one or all of the reasons discussed above, Appellant submits that Green does not anticipate Claim 30 and that Claim 30 is in condition for allowance. Claims 31-33 depend from Claim 30. For at least the reasons discussed above with respect to Claim 30, *inter alia*, Appellants respectfully submit that Claims 31-33 are in condition for allowance.

Therefore, Appellant submits that the rejection of Claims 31-33 under 35 U.S.C. § 102(b) should be reversed.

D. Bulow In View Of Williamson Fail To Render Obvious The Surgical Instrument As Recited In Claims 18-20

Claims 18-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bulow in view of Williamson. Appellant respectfully submits that Bulow in view of Williamson fail to disclose each and every element recited in independent Claim 1, either expressly or inherently.

With reference to FIG. 1 of Williamson, reproduced below, Williamson discloses a endoscopic linear cutting and stapling instrument 10 configured to be used in conjunction with an impedance feedback device 70. The stapling instrument 10 includes a housing 16 coupled to

a sheath 30 with a lumen extending therethrough and an end effector 15 extending from the distal end of the sheath 30.

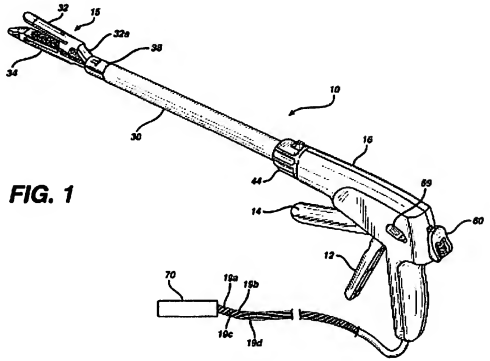


FIG. 1

Williamson does not provide any disclosure which cures the deficiencies of Bulow with respect to Claim 1 as discussed above. Since Claims 18-20 depend indirectly from Claim 1, for at least the reasons discussed above with respect to Claim 1, Appellant believes that Claims 18-20 are also in condition for allowance.

Therefore, Appellant submits that the rejection of Claims 18-20 under 35 U.S.C. § 103(a) should be reversed.

E. Jespersen Fails To Render Obvious, The Method Of Performing A Surgical Procedure As Recited In Claims 21, 25 and 26

Claims 21, 25 and 26 stand rejected under 35 U.S.C. § 103(a) as being obvious Jespersen. Appellant respectfully submits that Jespersen fails to disclose each and every element recited in independent Claim 21, either expressly or inherently.

Claim 21 recites the steps of "providing a surgical instrument including...a cover deployment device...the cover deployment device being positioned on the body portion and the cover being positioned about the cover deployment device..." and "moving the cover from the first position to the second position by advancing the cover deployment device to invert the cover at least partially over the tool assembly...".

Contrary to the Examiner's assertion, a person of ordinary skill in the art would not modify forceps 44 such that they are positioned on the body portion of a surgical instrument, nor would it be obvious to position the forceps between the body portion and the cover. Certainly, the specification of Jespersen is totally devoid of such a teaching or suggestion. Thus, Appellant respectfully submits that independent Claim 21 is patentable over Jespersen and is in condition for allowance. Since claims 25 and 26 depend from claim 21, for at least the same reasons, claims 25 and 26 are in condition for allowance.

Therefore, Appellant submits that the rejection of Claims 21, 25 and 26 under 35 U.S.C. § 103(a) should be reversed.

F. Jespersen In View Of Williamson Fails To Render Obvious The Surgical Instruments As Recited In Claims 18-20, 22-24 and 30

Claims 18-20, 22-24 and 30 stand rejected under 35 U.S.C. § 103(a) over Jespersen in view of Williamson. Appellant respectfully submits that Jespersen in view of Williamson fails to disclose each and every element recited in independent Claims 1 and 21, either expressly or inherently.

Claims 18-20 depend indirectly from Claim 1 and claims 22-24 depend from claim 21. As discussed above, Williamson discloses an endoscopic linear cutting and stapling instrument configured to be used in conjunction with an impedance feedback device. Williamson does not cure the deficiencies of Jesperson with respect to Claims 1 and 21, as discussed above. For at least the reasons discussed above with respect to Claims 1 and 21, Appellant believes that Claims 18-20 and 22-24 are also in condition for allowance.

Claim 30 recites a surgical instrument for insertion into a body lumen including, *inter alia*, "a cover deployment member positioned about the elongated body portion between the elongated body portion and the cover". As discussed above with respect to Claim 1, Jespersen fails to disclose a cover deployment member that is positioned about the elongated body portion of an instrument between the body portion and the cover. As also discussed above, Williamson does not provide any disclosure which cures the deficiency of Jespersen.

Therefore, Appellant submits that the rejection of Claim 30 under 35 U.S.C. § 103(b) over Jespersen in view of Williamson should be reversed.

G. **Conclusion**

In view of the foregoing analysis and remarks, it is clear that the surgical instrument of independent Claims 1 and 30 and the method of independent claim 21 are not anticipated or render obvious by Bulow, Jespersen, Green, Williamson or any proper combination thereof.

For at least the foregoing reasons, it is respectfully submitted that:

Claims 1, 2 and 6-17 are not anticipated under 35 U.S.C. § 102(b) in view Bulow, and this rejection should be reversed;

Claims 1, 2, 11 and 13-17 are not anticipated under 35 U.S.C. § 102(e) in view of Jespersen, and this rejection should be reversed;

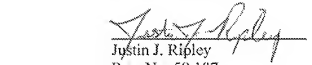
Claims 30-33 are not anticipated under 35 U.S.C. § 102(b) by Green, and this rejection should be reversed;

Claims 18-20 are not obvious under 35 U.S.C. § 103(a) over Bulow in view of Williamson, and this rejection should be reversed;

Claims 21, 25 and 26 are not obvious under 35 U.S.C. § 103(a) over Jespersen, and this rejection should be reversed; and

Claims 18-20, 22-24 and 30 are obvious under 35 U.S.C. § 103(a) over Jespersen in view of Williamson, and this rejection should be reversed.

Respectfully submitted,



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VIII. CLAIMS APPENDIX

1. A surgical instrument comprising:

a body portion;

a tool assembly supported on the distal end of the body portion;

an elongated cover supported about the body portion of the instrument, the elongated cover being formed from a collapsible material and having a substantially tubular configuration having open proximal and distal ends, the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly, wherein when the elongated cover is in the first position the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly as the elongated cover is moved from the first position to the second position; and

a cover deployment device at least partially disposed about the body portion between the body portion and the elongated cover when the elongated cover is in the first position, the cover deployment device being in releasable engagement with the cover and being advanceable along the body portion to move the cover from the first position to the second position.

2. A surgical instrument according to Claim 1, wherein the cover is liquid impermeable.

3-5. (Canceled).

6. A surgical instrument according to Claim 1, wherein the cover deployment device includes a sleeve slidably positioned about the body portion between a retracted and an advanced

position, the sleeve being slidable from the retracted position to the advanced position to move the cover from the first position to the second position.

7. A surgical instrument according to Claim 6, wherein the sleeve includes first and second half-sections, the first and second half-sections being urged into abutment with one another by at least one expandable member, the expandable member being expandable to permit the first and second half-sections to move outwardly with respect to each other.

8. A surgical instrument according to Claim 7, wherein the expandable member is a resilient O-ring.

9. A surgical instrument according to Claim 7, wherein the sleeve includes a proximally located annular ring dimensioned to facilitate movement of the sleeve between the retracted and advanced positions.

10. A surgical instrument according to Claim 7, wherein the first sleeve half-section includes at least one projection and the second sleeve half-section includes at least one slot, the at least one projection being slidable into the at least one slot to maintain alignment between the first and second half-sections when the half-sections move outwardly with respect to each other.

11. A surgical instrument according to Claim 1, wherein the cover defines a lumen and the cover is positioned about the body portion and the cover deployment device, wherein movement

of the cover deployment device from the retracted position to the advanced position inverts the cover over the tool assembly.

12. A surgical instrument according to Claim 11, wherein the cover deployment device includes a distal engagement member, a proximal guide portion and a central body portion interconnecting the engagement member and the guide portion, the cover deployment device being slidably supported on the body portion to enable the cover deployment device to be moved to move the cover to the second position.

13. A surgical instrument according to Claim 1, wherein the cover defines a lumen, the proximal end of the cover being movable over the tool assembly to at least partially encompass the tool assembly.

14. A surgical instrument according to Claim 13, further including a closure device for closing the proximal end of the cover after it has moved over the tool assembly.

15 . A surgical instrument according to Claim 14, wherein the closure device includes an elastic band supported by the cover.

16. A surgical instrument according to Claim 14, wherein the closure device includes a drawstring.

17. A surgical instrument according to Claim 16, wherein the distal end of the cover is removably fastened to the surgical instrument.

18. A surgical instrument according to Claim 17, wherein the surgical instrument is a circular stapler.

19. A surgical instrument according lo Claim 17, wherein the surgical instrument is an ultrasonic dissector.

20. A surgical instrument according to Claim 17, wherein surgical instrument is a linear stapler.

21. A method of performing a surgical procedure comprising the following steps:

providing a surgical instrument including a body portion, a tool assembly, a cover deployment device and a cover, the distal end of the cover being secured about the instrument adjacent a proximal end of the tool assembly, the cover deployment device being positioned on the body portion and the cover being positioned about the cover deployment device such that the cover is movable from a first position wherein the tool assembly is uncovered to a second position wherein the tool assembly is at least partially covered by advancing the cover deployment device along the body portion;

positioning the surgical instrument adjacent a surgical site and performing a surgical operation on desired tissue;

moving the cover from the first position to the second position by advancing the cover deployment device to invert the cover at least partially over the tool assembly; and

subsequently removing the surgical instrument from the surgical site, while maintaining the cover at least partially over the tool assembly.

22. A method according to Claim 21, wherein the surgical instrument is a circular stapler.

23. A method according to Claim 21, wherein the surgical instrument is a linear stapler.

24. A method according to Claim 21, wherein the surgical instrument is an ultrasonic dissector.

25. A method according to Claim 21, wherein the surgical instrument includes a closure device, and further including the step of actuating the closure device to close the cover at a location distally of the tool assembly.

26. A method according to Claim 25, wherein the closure device is a drawstring.

27-29. (Canceled).

30. A surgical instrument for insertion into a body lumen comprising:

an elongated body portion having a first diameter and an outer surface;

a stationary shell assembly supported on a distal end of the elongated body portion, the shell assembly having a plurality of surgical staples;

a cover fitted about the elongated body portion, the elongated cover movable from a first proximal position to a second position to cover the stationary shell assembly; and

a cover deployment member positioned about the elongated body portion between the elongated body portion and the cover, the cover deployment being slidable in a distal direction along the body portion to move the cover to the second position.

31. A surgical instrument according to Claim 30, wherein the cover deployment member is releasably engaged with the cover.

32. A surgical instrument according to Claim 31, wherein the cover deployment member includes a sleeve slidably positioned about the body portion between a retracted and an advanced position.

33. A surgical instrument according to Claim 32, wherein the sleeve is slidable from the retracted position to the advanced position to move the cover from the first position to the second position.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None